



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 17, 2015

C.R. Bard, Inc.
Aaron Conovaloff
Regulatory Affairs Associate
1625 West 3rd St.
Tempe, Arizona 85281-1740

Re: K142083

Trade/Device Name: True Flow Valvuloplasty Perfusion Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon Aortic Valvuloplasty Catheter
Regulatory Class: Class II
Product Code: OZT
Dated: March 3, 2015
Received: March 4, 2015

Dear Aaron Conovaloff,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". To the right of the signature is a small, faint watermark-like logo of the FDA seal.

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number (*if known*)

Device Name

True™ Flow Valvuloplasty Perfusion Catheter

Indications for Use (*Describe*)

The True™ Flow Valvuloplasty Perfusion Catheter is indicated for balloon aortic valvuloplasty.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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True™ Flow Valvuloplasty Perfusion Catheter

**510(k) Summary
21 CFR 807.92**

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-350-6012

Fax: 480-449-2546

Contact: Aaron Conovaloff, Regulatory Affairs Associate

Date: August 14, 2014

Subject Device Name:

Device Trade Name: **True™ Flow Valvuloplasty Perfusion Catheter**

Common or Usual Name: Balloon Aortic Valvuloplasty/Percutaneous Catheter (21 CFR 870.1255, Product Code OZT)

Classification: Class II

Classification Panel: Cardiovascular

Predicate Device:

- True Dilatation™ Balloon Valvuloplasty Catheter (K133569; cleared December 20, 2013)

Summary of Change:

The modifications from the predicate device, the True Dilatation™ Balloon Valvuloplasty Catheter, to the subject device, the True™ Flow Valvuloplasty Perfusion Catheter, include balloon design, balloon materials, catheter colorant, contraindications, and performance characteristics.

Device Description:

The True™ Flow Valvuloplasty Perfusion Catheter is an over-the-wire co-axial catheter with a balloon fixed at the tip. The balloon enables hemodynamic flow through its central orifice. The catheter is 110 cm long and has two lumens: one lumen is used to inflate and deflate the balloon and the other permits the use of a guidewire to position the catheter. The balloon inflation luer-lock hub (angled) connects to a syringe inflation device to deliver radiopaque contrast media for inflation. The guidewire luer-lock hub (straight) connects to the guidewire lumen. The balloon is non-compliant and is designed to reach a known diameter and length when inflated within the specified pressure range. Three radiopaque markers are embedded in the balloon wall. These bands are positioned at the proximal and distal balloon shoulders, and in the middle. These bands are provided for fluoroscopic positioning of the device across the aortic valve. Balloon catheter dimensions, nominal pressure, maximum inflation pressure, recommended introducer size, and maximum guidewire size are indicated on the package label.

Attribute	True™ Flow Valvuloplasty Perfusion Catheter Product Offering
Balloon Diameter (mm)	24
Balloon Length (cm)	3.5
Catheter Shaft Length (cm)	110
Introducer Sheath Compatibility	18F

Indications for Use of Device:

The True™ Flow Valvuloplasty Perfusion Catheter is indicated for balloon aortic valvuloplasty.

Comparison of Indications for Use to Predicate Device:

The indications for use statement for the True™ Flow Valvuloplasty Perfusion Catheter does not raise any new issues of safety and effectiveness as demonstrated through the risk analysis process based on the proposed indications for use statement as compared to the predicate devices. Therefore, the subject device, the True™ Flow Valvuloplasty Perfusion Catheter, is substantially equivalent to the predicate device.

Technological Comparison to Predicate Device:

The True™ Flow Valvuloplasty Perfusion Catheter has the following similarities to the predicate device, the True Dilatation™ Balloon Valvuloplasty Catheter (clearance to market via K133569 on December 20, 2014):

- Same intended use
- Same indications for use
- Same target population
- Same operating principle
- Same fundamental scientific technology
- Same sterility assurance level and method of sterilization

The True™ Flow Valvuloplasty Perfusion Catheter incorporates the following new technological features as compared to the predicate device:

- Change in balloon design and materials to allow hemodynamic flow through the balloon while inflated
- Change in marker band materials and positions
- Change in catheter shaft color
- Change in balloon proximal bond
- Change in hub bonding materials

- Change in strain relief design
- Addition of packaging component

Performance Data:

To demonstrate substantial equivalence of the subject device to the predicate device, its technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed on the subject device:

- Dimensional Testing
- Marker Band Alignment
- Dye Penetration
- Visual Inspection of Product
- Visual Inspection of Sterile Barrier Packaging Heat Seals
- Tip Morphology
- Trackability
- Sheath Compatibility
- Media Interaction
- Luer Interface
- Hub Stress
- Inflation/Deflation Time
- Fatigue to Failure
- Tip to Balloon Tensile
- Balloon Burst
- Catheter Leak
- Failure Mode
- Shaft Burst
- Catheter Elongation
- Hub to Shaft Tensile
- Balloon to Shaft Tensile

- Radiopacity
- Balloon Distensibility
- Perfusion Test
- Radial Force Test
- MEM Elution Test
- Kligman Maximization Test
- Intracutaneous Injection Test
- Systemic Injection Test
- Rabbit Pyrogen Test
- Hemolysis – Rabbit Blood Contact
- Complement Activation Test
- Prothrombin Time Assay
- In Vitro Thrombogenicity
- In Vivo Thrombogenicity

The following *in vitro* test was leveraged from the predicate True Dilatation™ device:

- Pouch Tensile

The results from these tests demonstrate that the technological characteristics and performance criteria of the True™ Flow Valvuloplasty Perfusion Catheter are substantially equivalent to the predicate device, and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusions:

The subject device, the True™ Flow Valvuloplasty Perfusion Catheter, met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The True™ Flow Valvuloplasty Perfusion Catheter is substantially equivalent to the legally marketed predicate device, the True Dilatation™ Balloon Valvuloplasty Catheter.